EXHIBIT 3

Arthrex Products
Matrix of Label Product&Development codes

B Hallett ...NOVEMBER 2005

					Braid - Sleeve			Core				Percentage of Suture (Approx.)		
Suture Spool Label	Pearsalls Product Code	Development construction code	Product	Size	Yarn Type	D'tex	Number of yarns	Yarn Type	D'tex	Number of yarns	Ply	UHMWPE	Polyester	Nylon
4-0B-F/W	37G153000	PS30	Blue Fiberwire	4 / 0	UHMWPE Polyester	55 33	4 4	N/A	N/A	N/A	N/A	62.5%	37.50%	N/A
3-0B-F/W	37G203000	PSC33	Blue Fiberwire	3 / 0	UHMWPE Polyester	55 49	4 4	UHMWPE	55	1	0	58.4%	41.6%	N/A
2-0B-F/W	37G302000	PS12/2	Blue Fiberwire	2 / 0	UHMWPE Polyester	111 61	4 4	UHMWPE	144	1	0	70.7%	29.3%	N/A
0B-F/W	37G351000	DT3.5-3	Blue Fiberwire	0	UHMWPE Polyester	111 61	6 6	UHMWPE	217	1	0	70.7%	29.3%	N/A
0W-F/W	38G351000	PS3.5-3	White Fiberwire	0	UHMWPE Polyester	111 61	6 6	UHMWPE	217	1	0	70.7%	29.3%	N/A
1B-F/W	37G401000	PS53	Blue Fiberwire	1	UHMWPE Polyester	144 113	6 6	UHMWPE	144	1	3	65.7%	34.3%	N/A
1W-T/W	36G401000	PS54	White Tigerwire	1	UHMWPE Polyester Nylon	144 95 78	6 5 1	UHMWPE	144	1	3	70.1%	25.7%	4.2%
1B-T/W	36G401000BLUE	PS55	Blue Tigerwire	1	UHMWPE Polyester Nylon	144 95 78	6 5 1	UHMWPE	144	1	3	70.1%	25.7%	4.2%
2B-F/W	37G500500	PS05T2	Blue Fiberwire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
2W-F/W	38G500500	PSO5W	White Fiberwire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
2W-T/W	36G500500	PSN14Na	White Tigerwire	2	UHMWPE Polyester Nylon	144 95 78	8 7 1	UHMWPE	144	1	3	68.1%	28.6%	3.4%
U/T 2W-FW	38A500500	PS05WU-a	White untreated Fiberwire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
5B-F/W	37G700250	PS07	Blue Fiberwire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
5W-F/W	38G700250	PSH 1/1	White Fiberwire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
5W-T/W	36G700250	PSNH 1	White Tigerwire	5	UHMWPE Polyester Nylon	217 190 78	8 6 2	UHMWPE	217	2	3	70.1%	26.3%	3.6%
See Note Below	See Note Below	PSH 1	Green Fiberwire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
3+4W-FW	38A600500	PS 34	White Fiberwire	3/4	UHMWPE Polyester	217 190	6 6	UHMWPE	144	1	3	60.3%	39.7%	N/A
3+4B-FW	38G600500	PS 34A	Blue Fiberwire	3/4	UHMWPE Polyester	217 190	6 6	UHMWPE	144	1	3	60.3%	39.7%	N/A

DEPUY MITEK
EXHIBIT 318
04cv12457

See Note Below	See Note Below	PS67A	White / Black TigerTail	1	UHMWPE Polyester Nylon	144 95 78	6 6 1	UHMWPE	144	1	3	66.7%	29.3%	4.0%
See Note Below	See Note Below	PS67B	Blue / Black TigerTail	1	UHMWPE Polyester Nylon	144 95 78	6 6 1	UHMWPE	144	1	3	66.7%	29.3%	4.0%
2W-T/T-46 2W-T/T-54	PSDH5-38 PSDH3-38	PSDH5-38A PSDH3-38A	White / Black TigerTail	2	UHMWPE Polyester Nylon	144 95 78	8 8 1	UHMWPE	144	1	3	65.4%	31.4%	3.2%
2B-T/T-46 2B-T/T-54	PSDH5-38 PSDH3-38	PSDH5-38B PSDH3-38B	Blue / Black TigerTail	2	UHMWPE Polyester Nylon	144 95 78	8 8 1	UHMWPE	144	1	3	65.4%	31.4%	3.2%
SPD-02-01B	95G-500-500	DPM1	Blue Fiberwire	2	PURITY Polyester	110 113	8 8	PURITY	165	1	3	60.3%	39.7%	N/A
SPD-02-01W	96G-500-500	DPM02	White Fiberwire	2	PURITY Polyester	110 113	8 8	PURITY	165	1	3	60.3%	39.7%	N/A
SPD-02-01TW	97G-500-500	DPM03	White Tigerwire	2	PURITY Polyester Nylon	110 113 78	8 7 1	PURITY	165	1	3	61.3%	35.2%	3.5%

FiberWire is a suture with an outer covering of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester braided over an UHMWPE core.
TigerWire is a version of white FiberWire suture with a black strand creating spiral markings along the entire length of the suture.
TigerTail is a version of FiberWire suture with a black strand that creates spiral markings along one-half the length of the suture.

NOTE
Suture Spool Label and Pearsalls Product Code have not been assigned to these products.

PRODUCT CODE IDENTIFICATION

UNTREATED	A	
MED COATED	G	
BLUE	37	
WHITE	38	
TIGERWIRE	36	Please state blue if required

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs. CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: PETER DREYFUSS

DATE: September 16, 2005

TIME: 8:59 a.m. to 1:54 p.m.

LOCATION: The Ritz-Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Les Smoak, CLVS

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A. Yes.
Q. Is it true then that the No. 2 FiberWire used in AR-7201 has the same braiding as any Arthrex product that has a No. 5 FiberWire in it?
A. Yes.
Q. Is it true then that the No. 2 FiberWire used in AR-7201 has the same braiding as any Arthrex product that has a No. 2-0 FiberWire in it?
A. Yes.
Q. Is it true then that the No. 2 FiberWire used in AR-7201 has the same braiding as any Arthrex product that has a 0 FiberWire in it?
A. I believe so.
Q. Is it true then that the No. 2 FiberWire used in AR-7201 has the same braiding as any Arthrex product that has a 2 -- Strike that. Let me rephrase that.
Is it true then that the No. 2 FiberWire used in AR-7201 has the same braiding as any Arthrex product that has a 3-0 FiberWire in it?
A. I don't know.
Q. And who would know that?
A. Tara Schaneville.
Q. Okay. Is it true then that the No. 2 FiberWire used in AR-7201 has the same braiding as any Arthrex product that has a 4-0 FiberWire used in it?

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A. I don't know.
Q. And Tara would also know that?
A. Correct.
Q. Okay. Other than the No. 2, 5, 0, 2-0, 3-0, and 4-0, are there any other size FiberWires sold by Arthrex?
A. Yes.
Q. Okay. What other sizes of FiberWire other than 2, 5, 0, 0-2, 0-3 -- Yeah, strike that.
What other sizes other than 5, 2, 0, 2-0, 3-0, and 4-0 are sold by Arthrex?
A. A FiberTape.
Q. Okay. Anything else?
A. No.
Q. And is the braid of TigerWire different than the braid used in the No. 2 FiberWire?
MR. TAMBURO: Object to the form.
Q. Do you understand the question?
A. Yes.
Q. Okay.
A. Yes.
Q. They are different?
A. The braid in -- I'm sorry. Please rephrase or repeat.
Q. Sure. Sure. Is the braid in any Arthrex TigerWire different than the braid used in Arthrex's No. 2 FiberWire?

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A. The braid, no.
Q. Are the materials used in any Arthrex TigerWire different than the braid -- than the materials used in Arthrex's No. 2 FiberWire?
MR. TAMBURO: Object to the form.
A. Yes.
Q. And how are they different?
A. There is a strand -- one carrier of PET is replaced by one carrier of nylon.
Q. Is that only difference in the braid between Arthrex's TigerWire products of any size and Arthrex's No 2 FiberWire?
A. Yes.
Q. So the coating is the same; is that right?
A. Yes.
Q. And the coating used on all Arthrex FiberWire products, TigerWire products is MED-2174; right?
A. Yes.
Q. Has any other coating been used by Arthrex at any time to coat any of Arthrex's FiberWire products or TigerWire products?
A. No.
MR. FALKE: Sal, during the course of the break, do you think you could try to contact Tara Schaneville

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to try to find the answer to I think the three questions of 2-0, 3-0 --
MS. VERRECCHIO: No, not 2-0.
MR. FALKE: Not 2-0. Right. 3-0, 4-0, and 0 just to find out if the braid used in those sizes is the same as No. 2.
MR. TAMBURO: The same as No. 2?
MR. FALKE: Right.
MR. TAMBURO: Sure.
MR. FALKE: Thanks.
Why don't we -- Can we take a break now and try to find out, because that will help out.
MR. TAMBURO: Sure.
VIDEOGRAPHER: Going off the record. We're off
(A short break was held from 9:46 a.m. to 9:58 a.m.)
VIDEOGRAPHER: Back on the record.
BY MR. FALKE:
Q. Over the break, did you have a chance to talk to Tara Schaneville?
A. Yes.
Q. Is the No. 0 FiberWire constructed -- Strike that.
Is the No. 0 FiberWire braided the same was as the No. 2 FiberWire in AR-7201?

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Q. How many carriers are used in the braiding and manufacturing of any Arthrex 2-0 FiberWire regardless of whether it's attached to a needle or an anchor or is a free-standing strand?
A. Eight.
Q. How many carriers are used in the braiding and manufacturing of Arthrex's 3-0 FiberWire regardless of whether it's attached to an anchor or a suture or a needle?
A. Eight.
Q. And how many carriers are used in the braiding and manufacturing of Arthrex's 4-0 FiberWire suture regardless of whether it's attached to an anchor or a needle?
A. Eight.
Q. So the Size 2-0, 3-0, and 4-0 FiberWire sutures used by Arthrex all use eight carriers in the braiding and manufacturing of them?
A. Correct.
Q. And the No. 2 FiberWire suture, No. 5 FiberWire suture, the No. 0 FiberWire suture, the No. 2-0 FiberWire suture, and the 3-0 FiberWire suture all have the same braiding process; right?
A. Yes.
Q. And the No. 4-0 FiberWire suture has a different

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braiding process than the 2, 5, 0, 2-0, and 3-0; right?
A. Yes.
Q. Okay. And other than the 2, 5, 0, 2-0, 3-0, and 4-0, are there any other size FiberWire that Arthrex sells?
A. Yes.
Q. What other sizes?
A. FiberTape.
Q. Okay. And does FiberTape have a size?
A. Two-millimeter FiberTape.
Q. Okay. We'll get into FiberTape later.
And I think we established earlier that the braiding of any size FiberLoop, FiberStick, FiberSnare is the same as the braid used in the No. 2 FiberWire suture in AR-7201; right?
MR. TAMBURO: Objection; mischaracterizes prior testimony.
A. As I understand, yes.
Q. Okay. Did you understand that question?
A. Yes.
Q. I believe you have in front of you Exhibit 102?
A. Yes.
Q. Could you look at that, please.
If you could, please -- Well, first, have you ever seen Exhibit 102 before?

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A. No. As a whole, no.
Q. You've seen parts of it though?
A. I believe so.
Q. Okay. If you could turn to ARM 8784, please, in Exhibit 102. Have you seen ARM 8784 in Exhibit 102 before?
A. No, I haven't.
Q. Do you know what is shown on ARM 8784 in Exhibit 102?
A. It appears to be a flow chart for manufacturing at Pearsalls.
Q. Can you take a look at and review ARM 8784 for me.
A. (Witness nods head affirmatively). Yes.
Q. Do you have an understanding of how Pearsalls braids the bulk suture used in Arthrex's FiberWire sutures and suture products?
A. Yes.
Q. Okay. And do you believe that the process flow chart on ARM 8784 accurately depicts the braiding process that Pearsalls uses to braid and manufacture the bulk sutures used in Arthrex's FiberWire sutures and suture products?
A. Yes.
Q. Okay. Currently, what materials are used in the

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manufacture of Arthrex's No. 2 FiberWire in AR-7201?
A. Ultra high molecular weight polyethylene, PET, silicone, and cyanoacrylate.
Q. Is it cyanoacrylate?
A. Acrylate. It's a Superglue, Loc-Tite.
Q. Okay. Any other materials used in the manufacture of Arthrex's No. 2 FiberWire?
A. Dye.
Q. Okay. Anything else?
A. Not that I'm aware of.
Q. Okay. So as far as you know, the only materials -- as far as Arthrex is aware, the only materials used to make Arthrex's No. 2 FiberWire in AR-7201 is ultra high molecular weight polyethylene, PET, silicone, Loc-Tite, and dye?
A. And if we're speaking of TigerWire, nylon.
Q. Okay. We're not talking TigerWire. We're just talking No. 2 FiberWire in AR-7201.
A. 7201 includes TigerWire.
Q. That's right. That's why I have been saying the No. 2 FiberWire in 7201.
A. They're both No. 2s.
Q. Right, but one's a TigerWire and one's a FiberWire; right?
A. Yes, the blue FiberWire in 7201.

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Q. Okay. Okay. When I have been saying today the No. 2 FiberWire in No. 7201, I have been referring to the blue FiberWire as opposed to the black and white TigerWire.
A. Understood.
Q. Okay. Did you understand that when I have been asking questions?
A. Yes, I have.
Q. Okay. Let me ask the question again. So as Arthrex believes the materials used in the manufacturing of the No. 2 FiberWire in AR-7201 are ultra high molecular weight polyethylene, PET, silicone, Loc-Tite, and dye?
A. Correct.
Q. And the silicone, is that the coating used in the No. 2 Arthrex FiberWire?
A. Yes.
Q. And what coating is used in Arthrex's FiberWire in AR-2 -- AR-7201?
A. I'm sorry. I --
Q. And what coat is used in Arthrex's FiberWire wire AR-7201?
A. I believe it's a silicone coating.
Q. Is it referred to as MED-2174?
A. Yes. Correct.
Q. And that's manufactured by a company called NuSil

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Technologies; is that right?
A. That's correct.
Q. Okay. Now I'd like to walk through the steps of what Pearsalls does to make the bulk sutures used in Arthrex's FiberWire; okay?
A. (Witness nods head affirmatively).
Q. And if we start on Page ARM 8784, the first step says incoming yarn to stores. Do you see that?
A. Yes.
Q. What does that mean?
A. That would mean that the yarns that are purchased from a regional manufacturer would be received, inspected and put into inventory for -- as good product for manufacturing.
Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire sutures?
A. Incoming yarns would be ultra high molecular weight polyethylene and PET.
Q. Where does Pearsalls obtain the ultra high molecular weight polyethylene used in manufacturing and braiding Arthrex's FiberWire sutures?
MR. TAMBURO: Objection; outside the scope.
A. I -- May I ask currently?
Q. Sure. Yes, currently for now.

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A. Currently --
Q. Let me ask another question to help you out. Does Arthrex provide to Pearsalls the ultra high molecular polyethylene used to manufacture and braid bulk sutures for Arthrex's FiberWires?
MR. TAMBURO: Same objection.
A. We have, yes.
Q. Currently do you; do you know?
A. Currently, I don't know.
Q. Okay. And other than Arthrex supplying the ultra high molecular polyethylene to Pearsalls, what other sources throughout the history of FiberWire has Pearsalls obtained the ultra high molecular weight polyethylene used in the manufacturing and braiding of Arthrex's FiberWire sutures?
MR. TAMBURO: Objection. The question is seeking an answer outside the scope of the topics that this witness is designated for.
A. I believe Dyneema. DSM Corporation.
Q. And for what periods did Pearsalls obtain Dyneema for use in the braiding and manufacturing of Arthrex's FiberWire sutures?
MR. TAMBURO: Same objection.
A. I don't know.
Q. Currently, what type of ultra high molecular

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polyethylene is used in the manufacturing of Arthrex's FiberWire sutures?
A. Speaking currently, it may be either Spectra or Dyneema in terms of the manufacture of the ultra high molecular weight polyethylene.
THE COURT REPORTER: The "manufacture"?
A. Of the procurement.
THE COURT REPORTER: "Procurement."
Q. But you're not sure what the current material used in the FiberWire is for ultra high molecular polyethylene?
A. No.
Q. Okay. Other than the ultra high molecular polyethylene that Pearsalls obtains to make the braid for Arthrex's FiberWire sutures, you mentioned that they also obtain PET; correct?
A. Correct.
Q. And what is PET?
A. It's polyester.
Q. And what type of polyester does Pearsalls use to braid Arthrex's FiberWire sutures?
A. I'm not sure.
Q. Do you know who or where Pearsalls obtains the PET used in the manufacturing of Arthrex's FiberWire sutures?

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A. Yes.
Q. Okay. And then let's get back to where we were. Yarn issue to winding for either. And I believe you said that Pearsalls then takes the incoming yarn in whatever form it's in and puts the polyester and the Dyneema or the polyethylene on various bobbins?
A. Yes.
MR. TAMBURO: Objection.
Q. Is that right?
MR. TAMBURO: I'm going to object; that mischaracterizes the testimony.
Q. Did I mischaracterize your testimony?
A. The yarn is issued to winding for winding onto a particular spool or bobbin that would aid in the manufacturing steps that would come thereafter.
Q. Mmm-hmm. Is the ultra high molecular -- Is the polyethylene and the PET when it's received by Pearsalls is the strand a monofilament?
MR. TAMBURO: Object to the form.
A. No.
Q. What is -- How do you characterize that strand of polyethylene when Pearsalls receives it?
MR. TAMBURO: Object to the form.
A. It is a various -- various individual filaments make up the yarn that's received. And the yarn may be

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several filaments to many.
Q. So what is an individual filament then?
A. An individual filament is -- you would liken it to a hair.
Q. Okay.
A. An individual filament would be a monofilament taken by itself.
Q. Okay. And then many monofilaments make up a yarn?
A. Correct.
Q. And how are they -- how were the monofilaments structured within the yarn?
A. I believe they may have a slight twist.
Q. Okay. So a yarn of polyethylene used in the FiberWire sutures is made up of many monofilaments twisted around each other --
MR. TAMBURO: Objection; assumes --
Q. -- is that fair?
MR. TAMBURO: Objection; assumes facts not in evidence. I object to the form.
A. Potentially.
Q. Have I assumed any facts in that question that we haven't talked about today?
MR. TAMBURO: Well, I would just --
MR. FALKE: I'm asking the witness.

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A. I'm not exactly sure on exactly how the yarn is received, so --
MR. TAMBURO: And I would clarify the witnesses's prior testimony has been ultra --
MR. FALKE: Is that an objection? Come on, Sal.
MR. TAMBURO: Yes, this is an objection. I would clarify that the witness's prior testimony has been polyethylene -- ultra high molecular weight polyethylene, and your questions are directed to something different.
And his prior testimony has stated that PET is used in FiberWire, and your questions are rephrasing that term, was well. I'm just trying to keep the record clear.
BY MR. FALKE:
Q. What is PET? Polyester; right?
A. PET is the particular polyester.
Q. So when I say polyester, I'm referring to the PET that's used in Arthrex's FiberWire sutures.
A. Yeah.
MR. TAMBURO: Is that a question?
Q. Yeah.
MR. TAMBURO: Okay.
A. If you're saying when you refer to polyester, we refer to -- it's referring to the PET.

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Q. Right, because when I asked you what PET was, you said polyester; right?
A. No, PET is a subset of polyester.
Q. Okay. But do you know what PET is used in the manufacturing of Arthrex's FiberWire sutures?
A. I'm not exactly sure.
Q. Okay. We were talking about how the individual monofilaments in the polyethylene or the ultra high molecular polyethylene are structured. And I think you said they were twisted; is that right?
A. I believe there may be a slight twist just to ease in handling.
Q. Okay. Okay. And then, again, down to the second step in ARM 8784, those strands are then put onto bobbins; is that what you said?
A. Yes.
Q. And what is a bobbin as used in ARM 8784?
A. A bobbin as a general term would be any round -- what would you call it --
Q. Spool?
A. -- a revolved shape that would allow you to wind something. It may or may not have end caps on it.
Q. But the bobbin is actually the thing that the sutures are wound around?
A. Sutures are wound around.

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Q. Okay.
A. Sutures, yarn, what have not.
Q. Right. In general, how big are these bobbins?
A. In general?
Q. Well, no. Let me ask the bobbins used in Pearsalls manufacture of Arthrex's FiberWire sutures, how big are the bobbins?
A. I would approximate them -- approximate about a foot -- 12 inches of length or less.
Q. Okay. And how -- and what length of the yarn of the PET and the ultra high molecular weight polyethylene are wound around the bobbins?
A. I'm not exactly sure.
Q. Okay. Generally?
A. Generally, it's --
Q. A hundred feet?
A. More than a hundred feet. Probably in excess of 182 or 300 meters.
Q. Okay. And then it says yarn issue dye the winding for core or cover; do you see that?
A. Yes.
Q. What does that mean?
A. At that point, they can either issue the yarn to a winding to -- which would then thereafter go into the cover portion of the product or they can issue it to be --

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to go to the process for the core.
Q. Okay. And what -- does every Arthrex FiberWire suture have a cover?
A. Yes.
Q. Has every Arthrex FiberWire suture sold by Arthrex had a cover on it?
A. Yes.
Q. Okay. And currently and historically, has every Arthrex FiberWire suture had a core in it?
A. No.
Q. Okay. When did Arthrex's FiberWire sutures have a core?
A. They have always had a core.
Q. Do they -- Okay. I think I asked and currently and historically, has ever FiberWire suture had a core and you said no; right?
A. Yes.
Q. Okay. And then I said when -- when did Arthrex's FiberWire sutures have a core. And then you said they've always had a core.
A. We have one product that does not have a core.
Q. Okay. And what product is that?
A. The 4-0 FiberWire.
Q. Okay. So currently and historically, every FiberWire suture other than the 4-0 has had a core and a

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cover; right?
A. Yes.
Q. And currently -- currently, the Arthrex 4-0 FiberWire suture does not have a core; right?
A. Correct.
Q. Has Arthrex's FiberWire suture -- 4-0 suture ever had a core?
A. No, not that I'm aware of.
Q. In Arthrex's FiberWire sutures presently, other than the 4-0 FiberWire, what is the core made of?
A. Ultra high molecular weight polyethylene.
Q. Is that it?
A. Yes.
Q. Okay. So in Arthrex's FiberWires -- all of Arthrex's FiberWire sutures except for 4-0, the core is made of solely ultra high molecular weight polyethylene?
A. Correct.
Q. And what about a cover? What is -- Currently, I think you said all Arthrex FiberWire sutures have a cover; right?
A. Yes.
Q. What materials make up the cover in each of Arthrex's FiberWire sutures?
A. Ultra high molecular weight polyethylene and PET.
Q. And has that always been the case?

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A. Yes.
Q. But at various points and times, you think that the ultra high molecular polyethylene was either Dyneema or Spectra; is that right?
A. Correct.
Q. Was it anything other than Dyneema or Spectra at any time?
A. Not that I'm aware of.
Q. Okay. So I think where we are now is Pearsalls has taken the incoming yarn, put it onto bobbins, and then have separated bobbins used for cores and separates bobbins used for carriers; is that right? I mean cores and covers?
A. Correct.
Q. Okay. So let's go down then -- let's go down the cover side on ARM 8784. What does that mean?
A. From the previous step, which was the yarn issue to winding, the yarn was issued to winding on the carrier bobbins which are the particular bobbins used for the carriers.
Q. Is the carrier bobbin different than the bobbin you just described earlier?
A. It's one of -- to me, a bobbin -- a bobbin and a spool might be different. A bobbin would have a post on it with no cap.

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Q. So this is back up to number one?
A. Correct.
Q. Okay.
A. They're on --
Q. The incoming yarn stage?
A. -- placed onto pegs or posts to keep them, for lack of a better word, in a vertical fashion.
Q. Okay.
A. The yarns that are let off, how ever many there are, are let off and are led around turning posts.
Q. Mmm-hmm.
A. And then to the end -- to the bobbin or the spool that it's going to be taken up on. And as the yarns go around the posts, it naturally puts a twist in them together. They're going around the post in an unorthodox fashion, if you will.
Q. Okay. So the twisting of the core yarns occurs with Pearsalls takes the incoming yarns and puts them on the bobbin?
A. Yes. For the core.
Q. Okay. So as shown on ARM 8784, do you see how it says twist after the yarn issue to winding for either; do you see that?
A. Yes.
Q. Is that right then or is that --

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A. That's correct.
Q. So does the -- To me, I read that to mean first the yarns for the core are put onto a bobbin, and then after they're put on a bobbin, they're twisted?
A. No, they --
Q. That's not right?
A. The yarns -- it's yarn issued to winding for either.
Q. Okay.
A. And then so the yarn is issued to a department.
Q. Okay.
A. That department receives those and would say -- they would have the next work instruction, I would assume.
Q. Mmm-hmm.
A. The block called twist.
Q. Mmm-hmm (affirmative).
A. And they would say -- take these yarns, put them on these fixtures, apply the twist to them, how ever many yarns there are, and wind them to a bobbin, which would be the next bubble in the flow chart.
Q. Okay. And so that bobbin down at the bottom is the core bobbin?
A. Correct.
Q. And that core bobbin contains a length of several different yarns that have been twisted together, depending

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on the size of the FiberWire suture; is that right?
A. Correct.
Q. Okay. And then like we talked about earlier, each individual yarn is composed of mono -- several monofilaments?
A. Correct.
Q. Okay. Now I believe we talked about the ultra high molecular weight polyethylene is a yarn that's composed of many monofilaments; is that right?
A. Correct.
Q. What about the polyester -- or the PET? How is the PET -- how is the yarn of PET structured?
A. In the same fashion.
Q. Same way? So the PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET?
A. Correct.
Q. Okay. Okay. So right now we have in the manufacturing process -- and the steps we've talked about so far, does this apply to all of Arthrex's FiberWire sutures and TigerWire sutures?
A. With the exception of the 4-0 suture.
Q. Right. The only difference between the 4-0 suture is that there's no core bobbin? It's just --
A. Correct.

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Q. Okay. Now in the -- the bobbin used to make the cover, the individual yarns are not twisted together; right?
A. Correct.
Q. Okay. Could you initial or put your name on that and date it? And then use whatever title you think best describes what's shown in the picture. To me, it's incoming yarn to core bobbin, but if that's not accurate, please change it.
A. Today's date is the --
Q. 16th. I'm going to mark this Exhibit 117.
(DePuy Mitek Exhibit No. 117, drawing by Peter Dreyfuss of Twisting Process for Core Production of FiberWire, was marked for identification.)
Q. And could you draw then on -- I think I gave you another sheet of paper.
A. Yes, you did.
Q. Could you draw in just as much detail as you need the process from the incoming yarns to the bobbins used for the cover of the FiberWire sutures.
A. That would be --
Q. Or maybe just describe it with reference to Exhibit 117.
A. The difference would be very simple. There's the cover yarns used in FiberWire are only one yarn.

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Q. And I don't know if you did, but could you please label the core and the cover?
A. Yes, I did.
Q. Okay.
A. I was doing a core with three parts to represent the No. 2 suture. But since it's an 0, I'm not exactly sure how many yarns are made up of the core, but they're all UHMWP --
Q. Okay.
A. -- if that's acceptable.
Q. Okay. Yeah. Let me just take a look at it, please.
Okay. So but other than the core, which you're not quite sure of how many yarns make up the core on the 2-0, this outside accurately represents the cover or the sheath of the Arthrex 2-0 FiberWire?
A. Yes.
Q. Okay. And as you have shown, going around the cover or the sheath, the materials alternate PET, ultra high molecular weight polyethylene, PET, ultra high molecular weight polyethylene, et cetera?
A. Yes.
Q. Okay. Now within the sheath or the cover -- Well, first could you just label the sheath and the cover for me?

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A. (Witness complying).
Q. Are the individual yarns in the cover or sheath of the Arthrex 2-0 FiberWire as shown in 121 in contact with each other, meaning is the ultra high molecular weight polyethylene yarn connected to the neighboring PET yarn?
MR. TAMBURO: Object to the form.
A. They're all interdigitated. I'm sure there's contact between them.
Q. Intertwined?
A. Yes.
Q. Okay. So there is contact then between the neighboring or adjacent PET and ultra high molecular weight --
A. Yes.
Q. -- polyethylene yarns and the sheath or cover?
A. Yes.
Q. Okay. Next, if you could, could you please draw a cross-section of Arthrex's No. 2 FiberWire?
And -- I'm sorry. But before we go on, does Exhibit 121 reflect the construction or the structure of the 2-0 FiberWire as it's always been?
A. To the best of my knowledge, yes.
Q. Okay. So the construction with the structure as shown in 121 of a 2-0 FiberWire suture hasn't changed over

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time? Ever since Arthrex is manufacturing a 2-0 FiberWire, it's been using this configuration as shown in 121?
A. Yes.
Q. Okay.
A. (Witness complying).
Q. And I'm going to mark your drawing of Arthrex's No. 2 FiberWire suture as DePuy Mitek Exhibit 122.
(DePuy Mitek Exhibit No. 122, drawing of Peter Dreyfuss of the Approximate Cross-Section of No. 2 FiberWire, was marked for identification.)
Q. Can I take a look at it, please?
A. Yes.
Q. Okay. And so this shows a core made up of three ultra high molecular weight polyethylene yarns twisted together and then a cover or sheath composed of alternating yarns of ultra high molecular weight polyethylene and PET; is that right?
A. Correct.
Q. And the PET and ultra high molecular weight polyethylene that make up the sheath or cover of Arthrex's FiberWire No. 2 are in direct contact with each other; is that right?
A. Yes.
Q. Okay. And they're intertwined around each other;

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right?
A. They're braided.
Q. Okay. Is that intertwining or --
A. Yes, they're ...
Q. Okay. And does Exhibit 122 accurately reflect the construction of Arthrex's FiberWire No. 2 currently and since its release or since it was first sold by Arthrex?
MR. TAMBURO: Object to the form.
A. I believe so.
Q. Okay. Could you mark or title Exhibit 122?
A. (Witness complying).
Q. And next I was going to ask you to draw a cross-section of the No. 5 Arthrex FiberWire suture, which I believe is the same as Exhibit 122 that you have just drawn with the exception of possibly the number of yarns that comprise the core; is that right?
A. I believe that would be correct.
Q. Okay. And -- but the outside of the cover or sheath of the Arthrex FiberWire No. 2 is the same as the cover or sheath of the Arthrex FiberWire No. 2; right?
A. In the manner of braiding, yes.
Q. Right.
MR. TAMBURO: Object to the form.
Q. In the manner as you have shown in Exhibit

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No. 122?
A. Yes.
Q. I misspoke there, but the outside or the cover of the Arthrex FiberWire No. 5 is the same as the cover or sheath of the Arthrex FiberWire No. 2; is that correct?
A. That's correct.
Q. Okay. The same in terms of configuration and contact and intertwining; right?
A. Yes.
Q. Okay. Next, if I can ask you to draw the cross-section of Arthrex's No. 0 FiberWire.
A. Let's see.
Q. And I believe you testified earlier, and correct me if I'm wrong --
A. Twelve.
Q. -- that there's twelve carriers?
A. Correct.
Q. Okay. And I also believe you testified earlier that you weren't sure about how many yarns make up the core in Arthrex's Size 0 FiberWire; is that right?
A. That's correct.
Q. Okay.
A. I'm sorry; would you give me the number again?
MR. TAMBURO: Here.
A. All right.

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Q. Now I'm going to mark your drawing of a cross-section of Arthrex's No. 0 FiberWire with DePuy Mitek Exhibit 123.
(DePuy Mitek Exhibit No. 123, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 0 FiberWire, was marked for identification.)
Q. And I believe what you've drawn in Exhibit 123 is that the cover or sheath of the Arthrex No. 0 FiberWire has alternating yarns of PET and ultra high molecular weight polyethylene; is that right?
A. Correct.
Q. And that -- and that those neighboring yarns in the sheath or cover are in contact with each other?
A. Correct.
Q. And in the same configuration and intertwining manner as Exhibits 122 and 121?
A. Correct.
Q. Okay. Could you draw for me a cross-section of Arthrex's FiberWire 3-0 suture? I believe you testified earlier that it's eight carriers.
A. Thank you.
Q. And I'm going to label your cross-section drawing of Arthrex's FiberWire No. 3 suture with DePuy Mitek Exhibit 124.
(DePuy Mitek Exhibit No. 124, drawing of Peter

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Dreyfuss of the Approximate Cross-Section of Size 3-0 FiberWire, was marked for identification.)
Q. And just so the record's clear, all these hand drawings that you have done so far, when it says UHMW, that means ultra high molecular weight polyethylene?
A. Correct.
Q. Okay. And what you've shown is that Arthrex's No. 3-0 FiberWire has alternating yarns of PET and ultra high molecular weight polyethylene?
A. Correct.
Q. And that those neighboring yarns and the sheath or cover contact each other?
A. Correct.
Q. And they're in the same -- you know -- intertwining manner as Exhibits 123, 122, and 121?
A. Correct.
Q. And now if you could just draw for me a cross-sectional drawing of Arthrex's 4-0 FiberWire suture, please. And I'm going to mark your drawing of Arthrex's 4-0 FiberWire suture with DePuy Mitek Exhibit 125.
A. (Witness complying).
(DePuy Mitek Exhibit No. 125, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 4-0 FiberWire, was marked for identification.)
Q. And I believe what you've shown in Exhibit 125 is

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that, one, there's no core in the 4-0 FiberWire; right?
A. Correct.
Q. And that the sheath or cover is made up of intertwining yarns of ultra high molecular weight polyethylene and PET?
A. Correct.
Q. And that the neighboring yarns within the cover or sheath are in contact with each other?
A. Correct.
Q. Okay. Do Exhibits 123, 124, and 125 show not only the present-day but the configuration of the FiberWire sutures as sold in the past?
A. Yes, to the best of my knowledge and --
Q. In other words, there hasn't been any different configurations of Arthrex's 0, 3-0, and 4-0 FiberWire sutures?
A. I'm not for certain on the 4-0.
Q. Okay. But for the 2-0 and the -- or for the 0 and the 3-0 you are?
A. Yes.
Q. Okay. And I don't think I asked you this, but in Exhibit 125, the alternating sheaths -- alternating yarns and the sheath or cover are in intertwining contact like Exhibits 124, 123, 122, and 121?
A. Yes.

EXHIBIT 5

FiberWire™

IMPORTANT PRODUCT INFORMATION
WICHTIGE PRODUKTINFORMATION
NOTICE D'UTILISATION IMPORTANTE
IMPORTANTI INFORMAZIONI PER L'USO
INSTRUCCIONES IMPORTANTES PARA EL USO

CE 0086

Arthrex

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Arthrex

DFU-0065
Rev. 5

Description:
Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:
Arthrex FiberWire is indicated for use in soft tissue approximation and or ligation. FiberWire is not for use in cardiac indications.

Actions:
Arthrex FiberWire, when tested per ISO/DIS 10993, *Biological Evaluation of Medical Devices-Part 10: Tests for Irritations and Sensitization*, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:
None known

Warnings:
Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharps" containers.

Adverse Reactions:
Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:
Arthrex FiberWire suture is supplied sterile.
Method of sterilization - EO
Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:
Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:
The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

- Do not reuse
- QTY — Quantity
- STERILE EO — Sterile unless the package is damaged or open. Method of sterilization - EO
- STERILE R — Sterile unless the package is damaged or open. Method of sterilization - gamma radiation
- LOT — Lot number
- See package insert
- CE — The product meets the essential requirements of Medical Device Directive 93/42 EEC.
- Use by - year & month

Beschreibung:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (gesenkgeschmiedeten) Nadeln unterschiedlicher Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:
Arthrex FiberWire ist für Weichgewebeapproximation und/oder -ligation vorgesehen. FiberWire nicht für Kardio-Indikationen verwenden.

Funktionen:
Tests bei Arthrex FiberWire gemäß ISO/DIS 10993, *Biological Evaluation of Medical Devices - Part 10: Reiz- und Sensibilisierungstests* ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde *in vivo* keine signifikante Änderung der Zerreißfestigkeit festgestellt.

Gegenanzeigen:
Unbekannt

Warnhinweise:
Nicht resterilisieren. Unbenutztes Fadenmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschließen von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbarer Faden verwendet wird, da das Dehiszenzrisiko je nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Salzlösungen, (wie sie z.B. im Harn- und Gallentrakt vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von infizierten oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:
Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schäden durch Zusammendrücken oder Abklemmen mit chirurgischen Instrumenten wie Zangen oder Nadelhaltern nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Knotenhaltbarkeit ist die Verwendung von flachen, quadratischen Schleifen mit zusätzlichen Verknotungen, je nach chirurgischer Situation und Erfahrung des Chirurgen. Besonders beim Verknoten von monofilen Fäden sind unter Umständen zusätzliche Verknotungen angebracht. Sorgfältig vorgehen, um Schäden am umgebenden Gewebe und Benutzerpunktierung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Umformen an Stärke verlieren und gegen Verbiegen und Abbrechen weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:
Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Faden üblichen Reaktionen zählen unter Umständen Dehiszenz, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Salzlösungen (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeentzündungen, Schmerzen, Ödeme und Erythema an der Wundstelle. Versehentliches Stechen mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:
Arthrex FiberWire wird steril geliefert.
Sterilisationsmethode - EO.
Nicht resterilisieren. Bei beschädigter oder zuvor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

Lagerungsbedingungen:
Unter 25 °C trocken und fern von direkter Hitzeeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadenmaterial wird steril in vorgeschnittenen Längen und in manchen Fällen mit gesenkgeschmiedeten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

- Nicht wiederverwenden!
- QTY — Quantität
- STERILE EO — Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - EO
- STERILE R — Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - Bestrahlung
- LOT — Chargenbezeichnung
- Siehe Packungsbeilage
- CE — Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates über Medizinprodukte 93/42/EWG.
- Verwendbar bis Jahr und Monat

FRANÇAIS

Description:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Arthrex FiberWire est également commercialisée avec des aiguilles serties de différentes tailles. Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des noeuds et le passage du fil à travers les tissus. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou teintée, et elle est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:
La suture Arthrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Arthrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Réactions:
Aucune réaction allergique ou sensible n'a été observée lors de la soumission de la suture Arthrex FiberWire au test exigé par la norme ISO/DIS 10993 *I Evaluation biologique des dispositifs médicaux, Partie 10 : Essais d'irritation et de sensibilisation*. La suture teintée et le traitement en surface de la suture sont pharmacologiquement inactifs.

La suture Arthrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Arthrex FiberWire ne change pas de manière *significative in vivo*.

Contre-indications:
Aucune contre-indication connue.

Précautions d'emploi:
Ne pas stériliser à nouveau. Jeter toute suture non utilisée dont l'emballage a été ouvert. Ne pas exposer à la chaleur.

Tout praticien suturant une plaie avec la suture Arthrex FiberWire doit être familiarisé aux techniques chirurgicales recommandées pour les matériaux non résorbables, car le risque de déhiscence de la plaie varie selon le site de l'intervention et selon le type de suture employé.

Comme avec tout matériau exogène, un contact prolongé de cette suture ou de tout autre fil avec un fluide salin, comme ceux circulant dans les voies urinaires ou biliaires, peut conduire à la formation de calculs. Le praticien devra respecter les règles chirurgicales relatives au drainage et à la fermeture de plaies infectées ou contaminées.

Précautions d'emploi:
Comme avec toute autre suture, éviter d'abîmer le fil lors de sa manipulation. Ne pas écraser le fil avec des instruments chirurgicaux comme une pince ou un porte-aiguille.

Réaliser tous les noeuds conformément aux techniques chirurgicales en vigueur. Opter pour le noeud plat, qui garantit une bonne sécurité et qui est largement utilisé, avec boucles supplémentaires en fonction du cas chirurgical et de l'expérience du praticien. Si le fil est monofilament, prévoir des boucles supplémentaires pour les noeuds. Bien contrôler la pointe de l'aiguille pour éviter de piquer les tissus environnants ou de blesser le praticien.

Ne pas saisir l'aiguille par sa pointe ou par son attache sur le fil pour éviter de l'endommager. Eviter de modifier la courbure des aiguilles pour ne pas réduire leur résistance à la déformation et à la rupture. Après usage, jeter les aiguilles dans un récipient spécial pour objets pointus et tranchants.

Effets indésirables:
Aucun effet indésirable particulier n'a été observé lors des tests du fil Arthrex FiberWire chez l'animal. Comme avec les autres fils de suture non résorbables, les réactions suivantes sont possibles : déhiscence de la plaie, formation de calculs dans les voies urinaires ou biliaires si contact prolongé avec des fluides salins comme l'urine ou la bile, infectivité bactérienne accrue, inflammation tissulaire minime, douleur, oedème et érythème au niveau de la plaie. Toute blessure avec une aiguille chirurgicale contaminée peut transmettre des germes pathogènes présents dans le sang.

Stérilisation:
La suture Arthrex FiberWire est livrée stérile.
Méthode de stérilisation : oxyde d'éthylène
Ne pas stériliser à nouveau. Ne pas utiliser si l'emballage est ouvert ou endommagé. Jeter les sutures non utilisées si leur emballage est ouvert.

Conditions de stockage:
Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différentes longueurs précoupées. Elle est aussi disponible avec des aiguilles serties. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou en couleurs (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des noeuds et le passage du fil à travers les tissus.

SYMBOLES UTILISÉS SUR L'ÉTIQUETAGE

Ne pas réutiliser — QTY Quantité
STERILE EO Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - EO
STERILE R Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - irradiation
LOT No. de lot — Consulter la notice accompagnant le produit
CE Ce produit est conforme aux exigences de la directive sur les dispositifs médicaux CEE 93/42.
À utiliser avant le (mois/année)

ITALIANO

Descrizione:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). FiberWire Arthrex può essere venduto anche con aghi di varie dimensioni attaccati (saldati) alle estremità. La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Arthrex è disponibile sia non tinto (bianco) che tinto e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:
FiberWire Arthrex è indicato per l'approssimazione e/o la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Azioni:
FiberWire Arthrex, quando testato per ISO/DIS 10993, *Valutazione biologica dei dispositivi medici-Parte 10: I test per irritazioni e sensibilizzazione*, non hanno evidenziato reazioni allergiche o ipersensibilità. La sutura e il rivestimento tinti sono farmacologicamente inattivi.

FiberWire Arthrex non viene assorbito, ma può essere incapsulato nei tessuti connettivi circostanti. Non sono noti per FiberWire Arthrex cambiamenti significativi nella resistenza alla tensione *in-vivo*.

ControIndicazioni:
Nessuna nota

Avvertenze:
Non risterilizzare. Una volta aperte, gettare le suture non utilizzate. Non esporre al calore.

Gli utenti devono conoscere bene le procedure e le tecniche chirurgiche relative alle suture non assorbibili prima di utilizzare FiberWire Arthrex per la chiusura delle ferite, in quanto il rischio di deiscenza della ferita può variare in base al sito di applicazione ed al materiale utilizzato per la sutura.

Come per qualsiasi corpo estraneo, il contatto prolungato di questa e qualsiasi altra sutura con soluzioni saline, come quelle presenti nel tratto urinario o biliare, può risultare nella formazione di calcoli. È necessario seguire una pratica chirurgica corretta per il drenaggio e la chiusura di ferite infette o contaminate.

Precauzioni:
Nel trattare questo o qualsiasi altro materiale per sutura, occorre fare attenzione ad evitare danni dovuti al maneggiamento. Evitare danni da schiacciamento o piegature dovuti all'applicazione di strumenti chirurgici, inclusi forcipi o porta-aghi.

Assicurarsi che tutti i nodi siano stati legati usando le tecniche chirurgiche di annodatura accettate. Una sicurezza adeguata del nodo richiede la tecnica chirurgica accettata di legature piatte e quadrate, nonché di ulteriori avvolgimenti in base al caso chirurgico e all'esperienza del chirurgo. L'uso di avvolgimenti aggiuntivi può essere particolarmente appropriato per l'annodamento di monofilamenti. Evitare di recare danni al tessuto circostante o alla puntura dovuti ad una manipolazione non corretta della punta dell'ago.

Non afferrare l'ago per la punta o dalla saldatura, onde evitare danni a queste aree. Il riadattamento degli aghi può indebolirli e renderli meno resistenti alle piegature ed alle rotture. Gettare gli aghi usati in contenitori per materiale «affilato».

Effetti indesiderati:
Non si sono riscontrati effetti indesiderati con l'uso del prodotto FiberWire Arthrex nei test sugli animali. Le reazioni comuni alle suture non assorbibili possono includere la deiscenza della ferita, la formazione di calcoli nei tratti urinario e biliare dovuta al contatto prolungato con soluzioni saline come urina e bile, infettività batterica elevata, minima reazione del tessuto alle infiammazioni acute, dolore, edema ed eritema al sito della ferita. Il contatto involontario dell'ago con aghi chirurgici contaminati può risultare nella trasmissione di patogeni veicolati dal sangue.

Sterilizzazione:
La sutura FiberWire Arthrex viene fornita sterile.
Metodo di sterilizzazione - EO
Non risterilizzare. Non utilizzare se la confezione è aperta o danneggiata. Gettare le suture aperte non utilizzate.

Condizioni di conservazione:
Conservare al di sotto di 25°C, lontano da umidità e calore diretto. Non utilizzare dopo la data di scadenza.

Come si presenta:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro. La sutura viene fornita sterile in lunghezze pretagliate ed in alcuni casi con aghi saldati. FiberWire Arthrex è disponibile tinto o non tinto (bianco). La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

SIMBOLI USATI SULL'ETICHETTA

Monouso — QTY Quantità
STERILE EO Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - EO
STERILE R Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - Raggi Gamma
LOT Numero di lotto — Fare riferimento all'inserto contenuto nella confezione
CE Il prodotto è conforme ai requisiti essenziali della Direttiva CEE 93/42 sui Dispositivi Medici.
Da usarsi entro anno e mese

ESPAÑOL

Descripción:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la sutura FiberWire de Arthrex en diversos tamaños y con agujas incorporadas (enhebradas) en los extremos. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido. La sutura FiberWire de Arthrex viene en modelos sin teñir (blanca) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:
La sutura FiberWire de Arthrex está indicada para aplicaciones de aproximación y ligadura de tejido blando. La sutura FiberWire no está indicada para uso cardíaco.

Acciones:
Sutura FiberWire de Arthrex, sometida a prueba de acuerdo con la norma ISO/DIS 10993, *Evaluación Biológica de Dispositivos Médicos-Sección 10: En pruebas para detección de irritaciones y sensibilidad*, no hubo reacciones alérgicas ni de sensibilidad. La sutura teñida y el recubrimiento son inactivos farmacológicamente.

La sutura FiberWire de Arthrex no se absorbe, pero podría encapsularse en los tejidos conjuntivos adyacentes. La sutura FiberWire de Arthrex no presenta cambios significativos conocidos en cuanto a resistencia a la tracción *in vivo*.

Contraindicaciones:
Ninguna conocida

Advertencias:
No esterilizar de nuevo. Una vez abierto el paquete, desechar la sutura no utilizada. No exponer al calor.

Los usuarios deberán conocer los procedimientos quirúrgicos y las técnicas con suturas no absorbibles antes de utilizar FiberWire de Arthrex para cerrar heridas, ya que el riesgo de dehiscencia de las heridas varía según el sitio de aplicación y el material de sutura utilizado.

Al igual que ocurre con todo cuerpo extraño, el contacto prolongado de esta sutura, o de cualquier otro tipo de sutura, con soluciones salinas como las halladas en los tractos urinario o biliar, podría producir cálculos. Se deben usar métodos quirúrgicos aceptables en relación con el drenaje y cierre de heridas infectadas o contaminadas.

Precauciones:
Se debe tener cuidado al manipular este o cualquier otro material de sutura para evitar dañarlo. No utilice instrumentos quirúrgicos o de aplicación tales como fórceps o porta-agujas para evitar aplastar o plegar el material.

Cerciórese de que todos los nudos se hayan fijado por medio de técnicas aceptadas para nudos quirúrgicos. Para la fijación correcta de los nudos es necesario utilizar la técnica quirúrgica aceptada de nudos planos y cuadrados con lazadas adicionales, según lo requieran las condiciones quirúrgicas y la experiencia del cirujano. El uso de lazadas adicionales podría ser especialmente útil en la elaboración de nudos de monofilamentos. Debe tenerse cuidado para evitar daños al tejido adyacente o punciones producidas por el usuario al manipular incorrectamente la punta de la aguja.

No sujete la aguja por la punta ni por el ojo para evitar daños en esas partes. Si se modifica la forma de las agujas, éstas podrían perder su firmeza y ser menos resistentes a las curvaturas y el rompimiento. Deseche las agujas usadas en recipientes para objetos punzantes.

Reacciones adversas:
No se han detectado reacciones adversas del producto FiberWire de Arthrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: dehiscencia de las heridas, formación de cálculos en los tractos urinario y biliar en condición de contacto prolongado con soluciones salinas tales como la orina y la bilis, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y eritema en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Esterilización:
La sutura FiberWire de Arthrex se suministra estéril.
Método de esterilización - EO
No esterilizar de nuevo. No utilizar si el paquete llega abierto o dañado. Desechar las suturas abiertas que no se hayan utilizado.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25° C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en cortes de longitud predeterminada y en algunos casos con agujas enhebradas. La sutura FiberWire de Arthrex se encuentra disponible en modelos sin teñir (blanca) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

SIMBOLOS UTILIZADOS EN LAS ETIQUETAS

No reutilizar — QTY Cantidad
STERILE EO Estéril mientras el envase no sea abierto o dañado. Método de esterilización - EO
STERILE R Estéril mientras el envase no sea abierto o dañado. Método de esterilización - irradiación
LOT Número de lote — Ver folleto en el interior del paquete
CE Este producto cumple con las normas básicas de la Directiva de productos médicos, 93/42 CEE.
Caduca - año y mes

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

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The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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1 why the inventors should be precluded from
2 covering coated sutures with their patent?
3 A. No, I don't have any opinion.
4 Q. Okay. Do you have patents?
5 A. Yes.
6 Q. Okay. And in your patents, do you list
7 things that are claimed?
8 A. In my patent, yes, I do.
9 Q. Okay. Do you describe things in your
10 patents that may or may not be included within the
11 invention, in the description of the invention?
12 A. I don't remember what my -- I don't have
13 the patent in front of me.
14 Q. Well, in the claims, do you list every
15 possible feature of the invention?
16 MR. TAMBURO: Objection, vague.
17 THE WITNESS: I tried to.
18 BY MR. BONELLA:
19 Q. But do you list -- don't you try to get as
20 broad a claim as you can to cover as broad a
21 concept of your invention?
22 MR. TAMBURO: Objection, vague. He's not a
23 patent attorney.
24 THE WITNESS: I write what I -- my
25 invention is, and patent attorney actually

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1 formalize all of this.
2 BY MR. BONELLA:
3 Q. Okay. And --
4 A. So, I cannot say anything more than that.
5 Q. You didn't want the broadest protection
6 possible on your patents?
7 A. Whatever the patent attorney wants --
8 MR. TAMBURO: Objection, misrepresents the
9 testimony. Give me a chance to object, Debi.
10 BY MR. BONELLA:
11 Q. But the patent attorney does?
12 A. Yes.
13 Q. Okay. So, it's not what you want in your
14 patents; it's what the patent attorney wants in
15 terms of protection?
16 A. Well, I provide the information, it's a
17 back and forth --
18 Q. Right.
19 A. -- and I might say, well, it should be
20 included in this, but patent attorney is the final
21 one --
22 Q. Right.
23 A. -- who decides on the claims and the
24 writing part of the -- as you know.
25 Q. Right. And isn't it the goal with your

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1 invention, don't you want to try to protect as
2 broadly as possible?
3 A. Again, I may want something, but patent
4 attorney might come out with something different,
5 and Patent Office may come out with another
6 determination.
7 Q. If there's things in your patent that you
8 say may or may not be included within your
9 invention, but they're not listed in the claims,
10 do you think they should be excluded from the
11 claims in your patent?
12 MR. TAMBURO: Objection, calls for a legal
13 conclusion of a patent that we're not even -- that
14 we don't have in front of us and asking him to
15 interpret claim language of a patent we don't have
16 in front of us. This is ridiculous.
17 THE WITNESS: It's so hypothetical, I
18 cannot answer that question.
19 BY MR. BONELLA:
20 Q. You cannot answer it?
21 A. No.
22 Q. Okay. Do you see in the claim, claim 1 --
23 A. Uh-huh.
24 Q. -- it says, "A surgical suture consisting
25 essentially of a heterogenous braid," do you see

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1 that?
2 A. Yes.
3 Q. Is FiberWire a surgical suture?
4 A. FiberWire is a surgical suture, yes.
5 Q. Does FiberWire consist essentially of a
6 heterogenous braid?
7 A. Yes.
8 Q. Is FiberWire composed of a first and second
9 set of continuous and discrete yarns in a
10 sterilized, braided construction wherein at least
11 one yarn from the first set is in direct
12 intertwining contact with a yarn from the second
13 set?
14 A. Their construction is quite different from
15 this described here for FiberWire, what I know of
16 FiberWire.
17 Q. Well, FiberWire has a heterogenous -- has a
18 sheath that's a braid of ultra high molecular
19 weight polyethylene and PET, right?
20 A. Sheath of those two materials, yes.
21 Q. Braided together.
22 A. Right.
23 Q. Okay. Well, is that sheath of FiberWire,
24 is that a heterogenous braid?
25 A. Yeah, they are two different materials.

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Q. Okay. And is the FiberWire heterogenous braid composed of a first and second set of continuous and discrete yarns?
A. Yes.
Q. Okay. And is the FiberWire heterogenous sheath braid composed of discrete yarns in a sterilized braided construction?
A. Yes.
Q. And does the FiberWire heterogenous braided sheath have a braided construction where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set?
A. There is intertwining contact, yes.
Q. Okay. And in the next column, it says, "Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE."
Do you see that?
A. I see it.
Q. Does the FiberWire sheath have a yarn that meets that criteria?
A. No.
Q. Why?

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A. Because it has ultra high molecular weight polyethylene for its strength, and this PE does not include that ultra high molecular weight polyethylene.
Q. And that's your opinion?
A. Yes.
Q. Okay. And the next part says, "Each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group of PET, nylon and aramid."
Do you see that?
A. Yes.
Q. Does FiberWire meet that criteria?
A. It has the PET in it.
Q. So, it meets that criteria?
A. Uh-huh.
Q. And then it says, "Optionally a core."
FiberWire optionally has a core, right?
A. Right.
Q. Okay. If the Court defines PE, as used in that claim, to mean ultra high molecular weight polyethylene, if the Court defines PE to mean ultra high molecular weight polyethylene --
A. Not in this patent.
Q. No, if the Court --

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A. But that's -- the -- the FiberWire has ultra high molecular weight polyethylene core.
Q. Right.
A. Yes.
Q. If the Court says that PE, as used in the claims of the '446 patent, means ultra high molecular weight polyethylene, does FiberWire meet that clause (a) in column 9 of claim 1?
A. That's a hypothetical question. I cannot answer that.
Q. You can't answer it?
A. No.
Q. You can't provide an opinion one way or the other?
A. No.
Q. Okay. Claim 2, it says, "The surgical suture of claim 1 wherein the suture is attached to a needle."
Do you see that?
A. Yes.
Q. Is FiberWire sold attached to a needle?
A. Yes.
Q. Okay.
A. Not always, but I have seen the suture -- a needle with -- I mean a suture with a needle.

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Q. Okay, claim 8 says, "The surgical suture of claim 1 wherein the second set of yarns is PET."
FiberWire meets that criteria, right?
A. Yes.
Q. Claim 9 says, "The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent."
Do you see that?
A. I don't know at what percentage of PET and the ultra high molecular weight polyethylene is in the FiberWire.
Q. So, you don't have an opinion whether FiberWire meets that limitation?
A. No.
Q. Then in claim 12, it says, "The surgical suture of claim 8 wherein the suture is attached to the needle."
Do you see that?
A. Yes.
Q. FiberWire meets -- when FiberWire is sold attached to a needle, it meets that limitation?
A. Most of the time, but there is another non-needle part, too.
Q. Okay. You reviewed the prosecution history

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Publications

6. My publications include, among other things:

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986.

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites, TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux.

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos. 1/2/3, 1994.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

D. Patents

7. I am an inventor on the following U.S. Patents:

U.S. Patent 4,290,170 - "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.

U.S. Patent 4,497,866 - "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.

U.S. Patent 4,602,892 - "Sucker Rod," A braided composite rod and coupling for pumping oil.

U.S. Patent 4,841,613 - "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.

U.S. Patent 4,909,127 - "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.

U.S. Patent 5,004,474 - "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.

U.S. Patent 5,357,839 - "Solid Braid Structure" A 3-D system for producing braids.

U.S. Patent 5,358,758 - "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.

U.S. Patent 5,411,463 - "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.

U.S. Patent 5,501,133 - “Apparatus for Making a Braid Structure” A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.

U.S. Patent 5,697,969 - “Vascular Prosthesis and Method for Implanting” A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

E. Education

8. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

9. I have a Master of Science in Textile Technology from M.I.T., 1973.

10. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

11. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

12. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based, resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

13. A copy of my CV is attached under Tab A. A list of my publications and patents are set forth in my CV . Over the past four years, I have been deposed or testified as an Expert Witness in five cases. A complete list of cases in which I have provided testimony within the past four years is attached under Tab B. A list of the documents that I used in forming my opinions is set forth in Tab C.

14. I have been engaged by counsel of DePuy Mitek as a consultant in this litigation at a consulting rate of $300/hour.

II. Summary of Opinions

15. It is my opinion that sales of Arthrex's FiberWire™ and TigerWire™ suture products (in all sizes and regardless of whether it is attached to needle, or any other component)

literally infringe claims 1, 2, 8, 9, and 12 of U.S. Patent No. 5,314,446 (the '446 Patent) (Tab D). I understand that Arthrex sells FiberWire™ in the United States as free strands, attached to needles of various sizes, and attached to anchors used in various surgical applications (*e.g.*, rotator cuff repair, shoulder instability procedures). I further understand that Arthrex sells TigerWire™ in the United States attached to needles and anchors. I use the term "FiberWire™ suture products" to refer to all FiberWire™ products regardless of whether they are free strands, attached to needles, or attached to anchors. I use the term "TigerWire™ suture products" to refer to all TigerWire™ products regardless of whether they are sold attached to anchors or needles.

16. It is my opinion that sale of Arthrex's FiberWire™ and TigerWire™ suture products (in all suture sizes) directly infringes claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents.

17. I understand that Pearsalls imports into, and sells in, the United States unsterile, untipped FiberWire™ and TigerWire™. It is my opinion that such unsterile, untipped products are a component of the invention claimed in the '446 patent and constitute a material part of the invention claimed in claims 1, 2, 8, 9, and 12 of the '446 patent.

18. It is my opinion that the FiberWire™ and TigerWire™ sutures imported and sold by Pearsalls are especially adapted for use in infringement of claims 1, 2, 8, 9, and 12 of the 446 Patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use.

19. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ sutures are due to the invention, claimed in claims 1, 2, 8, 9, and 12 of the 446 Patent.

III. Materials Considered in Forming My Opinions

20. I understand that Arthrex has admitted that Pearsalls manufactures the Arthrex FiberWire™ and TigerWire™ suture. (Arthrex's Response to Mitek Interrogatory #2). I

attended the Pearsalls plant inspection and deposition in Taunton, Somerset, England on January 11, 2006. Mr. Brian Hallet testified on behalf of Pearsalls. While attending the Pearsalls plant inspection, I personally observed the manufacturing processes used to make the braid that comprises the FiberWire™ and TigerWire™ sutures. I may testify about the manufacturing process that I observed on January 11, 2006 at Pearsalls and the explanation of it as set forth by Pearsalls at depositions and in documents. I may use videotape deposition testimony or exhibits made from the videotape to aid me in testifying.

21. The manufacturing process to make the FiberWire™ and TigerWire™ suture braids that I observed includes the following steps: twisting core and sheath yarns, steam setting core and sheath, winding braider bobbins, braiding, winding to skein, scouring, dyeing, stretching, coating, and thermal treating, and subsequent inspection. I also observed Pearsall's testing laboratory. I may testify about each of these processes and the Pearsalls' equipment used in the manufacturing and testing processes. In addition to observing the manufacturing processes, I have also reviewed documents that describe them (DMI Exs. 279, 281, 287-312). I may rely on these documents in testifying about FiberWire™ and TigerWire™.

22. I have reviewed technical documents concerning FiberWire™'s and TigerWire™'s construction and manufacturing. I have also reviewed deposition transcripts of technical witnesses concerning FiberWire™ and TigerWire™, including the depositions of, among others, Arthrex Engineer, Peter Dreyfuss, Arthrex's Vice President of Operations Kevin Grieff, and Pearsalls' Brian Hallet. A list of the documents that I used in forming my opinions is set forth in Tab C.

23. I have examined samples of FiberWire™ and samples of FiberWire™ taken at various stages of the manufacturing processes (DMI Exs. 282, 283, 284, 285, 342 and Bates nos. ARM 25451-52, and ARM 25590).

IV. Legal Framework of My Opinions

I have been told by counsel to apply the following principles of United States Patent law in my analysis.

A. Direct Infringement

24. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

25. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

26. Infringement is “literal” when each claim limitation is literally present in a device. I understand that even if a device does not literally have each claim limitation, there is still infringement if the device has an equivalent of the claimed limitation that is not literally present. I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused

device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the '446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"direct intertwining contact" –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions provided by counsel.

B. Literal Infringement

28. I have been asked to provide my expert opinion regarding whether Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my opinion that Arthrex's FiberWire™ and TigerWire™ suture products infringe claims 1, 2, 8, 9, and 12 of the '446 Patent. It is my understanding that Arthrex has offered for sale or sold each of its FiberWire™ and TigerWire™ suture products within the United States. Therefore, there is literal infringement because, as described below, each of Arthrex's FiberWire™ and TigerWire™ suture products literally has all of the limitations of claims 1, 2, 8, 9, and 12. In determining literal infringement, I first consider the construction of FiberWire™ and TigerWire™. Then, I compare the claims, with the definitions as provided above, to the FiberWire™ and TigerWire™ suture products.

1. Arthrex's FiberWire™ and TigerWire™ Suture Products

29. I understand that all Arthrex's FiberWire™ suture, except size 4-0, is made of a core of polyethylene yarns (of the ultra high molecular weight type) and a braided sheath of polyethylene yarns (of the ultra high molecular weight type) and PET yarns (Dreyfuss 9/16/05 Dep. at 43, 55-57). The braided sheath is made by having one set of carriers, which have polyethylene, traversing the braider bed in a serpentine and clockwise fashion and the other set of carriers, which have PET, traversing the braider bed in a serpentine counter-clockwise fashion. I understand that Arthrex sells only sizes 5, 2, 0, 2-0, 3-0, and 4-0 FiberWire™ (Dreyfuss 9/16/05 Dep. at 31). I understand that the description of FiberWire™ is generally described in Arthrex's 510K for FiberWire™ (DMI Ex. 78 at ARM 001899).

30. I also understand that no. 2 Arthrex TigerWire™ is basically identical to no. 2 FiberWire™ with one exception. TigerWire™ has one black nylon yarn that replaces one of the PET yarns in no. 2 FiberWire™. No. 2 TigerWire™ has 8 yarns of PE, 7 yarns of PET, and 1 yarn of nylon braided together. (DMI Ex. 318) I also understand that Arthrex sells TigerWire™ in only size no. 2 (Dreyfuss 9/16/05 Dep. at 106). I understand that Arthrex also sells a TigerTail™[1] product that "is a version of FiberWire™ suture with a black strand that creates spiral marking along one-half length of the suture" (DMI Ex. 318).

31. I understand that FiberWire™ and TigerWire™ have been made with "Spectra" and "Dyneema" ultra high molecular weight polyethylene yarns in manufacturing the FiberWire™ suture (Dreyfuss Dep. p. 44-45, Grieff Dep. 9/15/05 p. 22-23, and 51). Spectra and Dyneema are trade names for certain companies' ultra high molecular weight polyethylene.

32. Arthrex's FiberWire™ and TigerWire™ suture is coated with NuSil Med-2174 manufactured by NuSil technology. (Dreyfuss 9/16/05 Dep. at 42). NuSil MED-2174 is generally described at DMI Ex. 78 at ARM 1933-36. I also understand that Arthrex sells a FiberStick™[2] product. I understand FiberStick™ to be a 50 inch piece of FiberWire™ that has 12 inches of its length stiffened with Loc-Tite (DMI Ex. 3 and Dreyfuss 9/16/05 Dep. at p. 122).

[1] Because TigerTail™ includes FiberWire™, TigerTail™ infringes the '446 patent for the same reasons that FiberWire™ infringes.

[2] Because FiberStick™ includes a portion of FiberWire™, FiberStick™ infringes the '446 patent for the same reasons that FiberWire™ does.

2. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 1

33. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[3] literally infringe claim 1 of the '446 because they literally have all of the limitations of claim 1 as set forth below.

Claim 1 of the '446 Patent	**FiberWire™ and TigerWire™ Suture Products**
A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and	The sterilized FiberWire™ and TigerWire™ suture is a braid of polyethylene (PE) and polyester (PET).[4] The PE and PET yarns are both continuous and discrete. The PE and PET are mechanically intertwined so that at least one PE yarn and one PET yarn are braided in direct intertwining contact. (DMI Ex. 318)
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The FiberWire™ and TigerWire™ suture is made from PE yarns that are made of a plurality of PE filaments. (Dreyfuss 9/16/05 Dep. at p. 50:21-51:1)

[3] I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3). To the extent that I have not recited a specific Arthrex product by name or code, if any unrecited product includes any portion of a FiberWire™ or TigerWire™ suture, it would infringe claims 1, 2, 8, 9, and 12 of the '446 patent for the same reasons stated herein.

[4] Q. And what incoming yarns are received by Pearsalls when Pearsalls manufactures and braids the bulk sutures made for Arthrex's FiberWire™ sutures?
A. Incoming yarns would be ultra high molecular weight polyethylene and PET. (Dreyfuss 9/16/05 Dep. at p. 43:15-19)

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon, and aramid; and	The FiberWire™ and TigerWire™ suture is made from PET yarns that are made of a plurality of PET filaments. (Dreyfuss 9/16/05 Dep. at p. 64:14-17)
c) optionally a core.	Arthrex's FiberWire™ sutures have a core except for 4-0 FiberWire™. (DMI Ex. 318)

34. I understand that Arthrex has contended that it does not infringe claim 1 of the '446 Patent for several reasons. To the extent that I understand these positions, I will address them here. I reserve the right to amend or supplement my opinions based on Arthrex's full explanation of its positions.

35. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

36. As explained above, I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating

is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (DMI Ex. 78 at ARM1976).

37. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Tab D at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (Tab D at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.[5]

38. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Tabs E (DMI Ex. 284), F (DMI Ex. 342), G (DMI Ex. 285).

[5] My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

39. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

40. It is my expert opinion and observation that the coating only appears on the surface of the braid.

41. I understand that Arthrex may argue that its FiberWire™ and TigerWire™ suture products do not literally infringe claim 1 because generally at least one end of its FiberWire™ and TigerWire™ suture products are "tipped." I also understand that Arthrex may argue that FiberStick™ does not infringe because about 12 of the 50 inches of its FiberStick™ product is stiffened. With respect to FiberWire™ & TigerWire™, tipping means stiffening the end of the suture with Loc-Tite. (Dreyfuss 9/16/05 Dep at p. 122). To the extent I understand Arthrex's position, I disagree with it.

42. In my opinion, the stiffening and tipping is irrelevant because the remainder of the FiberWire™, TigerWire™, and FiberStick™ suture products are not tipped or stiffened. Thus, at least a significant length of the FiberWire™, TigerWire™ and FiberStick™ suture products infringe. Therefore, regardless of the tipping and stiffening, FiberWire™, TigerWire™, and FiberStick™ infringe for the reasons set forth above.

43. Moreover, it is generally known that multifilament sutures have tipped ends so that they do not fray. Because the claims of the '446 patent are directed to a multifilament suture, it would not make sense for a multifilament suture claim to eliminate almost all multifilament sutures because of such a basic characteristic, *i.e.* tipped ends.

44. As explained above, Arthrex's TigerWire™ is substantially identical to Arthrex's FiberWire™ except that one carrier of PET yarn is replaced with a black nylon strand.

Otherwise, Arthrex's FiberWire™ braid is no different than Arthrex's TigerWire™ braid.[6] I understand that Arthrex contends that its TigerWire™ suture products do not infringe because they have one black nylon strand. To the extent that I understand Arthrex's argument, I disagree.

45. It is my opinion that the nylon marking strand in Arthrex's TigerWire™ suture is non-bioabsorbable and therefore does not materially affect the basic and novel characteristics of the invention in the '446 Patent. For one thing, nylon is expressly mentioned in claim 1 as one of the fiber-forming materials from which the second set yarn can be made. Thus, the inventors contemplated it as being part of their invention, not as changing the basic and novel characteristics of their invention. Further, the inclusion of nylon yarn instead of one yarn of PET (I understand that nylon makes up only 3.4% of TigerWire™ suture, DMI Ex. 318) does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed, at least one yarn of PE is in direct intertwining contact with a PET yarn, and the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture.

46. My opinion is supported by Mr. Dreyfuss' testimony. Mr. Dreyfuss testified on behalf of Arthrex that that the nylon in Arthrex's TigerWire™ suture products is for visual identification and has "minute differences in its feel and strength characteristics" (Dreyfuss 9/16/05 Dep. at p. 75:7-14). Since visual identification is not a basic and novel characteristic, the inclusion of a nylon marker band has no material effect on the basic and novel characteristics of the invention.

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[6] Q. Sure. Sure. Is the braid in any Arthrex TigerWire™ different than the braid used in Arthrex's No. 2 FiberWire™?
A. The braid, no. (Dreyfuss 9/16/05 Dep. at p. 31, line 24 – p. 32, line 2)

3. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 2

47. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products[7] literally have all of the limitations of claim 2.

Claim 2	**Arthrex's FiberWire™ and TigerWire™ needle products**
The surgical suture of claim 1 wherein the suture is attached to a needle.	Each FiberWire™ & TigerWire™ suture needle product has a FiberWire™ suture attached to a needle (DMI Ex. 3).

4. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 8

48. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[8] literally infringe claim 8 of the '446 for the following reasons:

Literal FiberWire™ Structure	**Claim 8**
The surgical suture of claim 1 wherein the second set of yarns is PET.	Each FiberWire™ and TigerWire™ suture product has PET as a second set of yarns.

[7] Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

[8] I understand that Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

	(DMI Ex. 318).

5. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Claim 9

49. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products[9] literally infringe claim 9 of the '446. I have used the following definition of "volume fraction of the first set of yarns in the braided sheath and core" which means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture. For the following reasons, FiberWire™ and TigerWire™ literally infringe claim 9 of the '446 patent for the following reasons:

Claim 9	**Arthrex's FiberWire™ and TigerWire™ Products**
The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to 80 percent.	Every Arthrex's FiberWire™ and TigerWire™ construction has a ratio of the cross-sectional area of UHMWPE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent. (DMI Ex. 318).

[9] Arthrex's FiberWire™ and TigerWire™ suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF, AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 3).

6. Arthrex's FiberWire™ and TigerWire™ Needle Products Literally Infringe Claim 12

50. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ needle products[10] literally have all of the limitations of claim 12.

Claim 12	Arthrex's FiberWire™ and TigerWire™ Needle Products
The surgical suture of claim 8 wherein the suture is attached to a needle.	Arthrex's FiberWire™ and TigerWire™ needle products have either a FiberWire™ or TigerWire™ suture attached to a needle. (DMI Ex. 3).

C. Arthrex's FiberWire™ and TigerWire™ Suture Products Literally Infringe Under the Doctrines of Equivalents

51. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial.

52. I understand that Arthrex contends that there is no literal infringement because the claim limitation with respect to the "first-fiber-forming material" is not present because, although FiberWire™ has "PE" or polyethylene, it has one type of "PE," ultra high molecular weight polyethylene (UHMWPE). If it is determined that "PE" as claimed does not mean

[10] Arthrex's FiberWire™ and TigerWire™ needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire™ or TigerWire™ suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (DMI Ex. 3).

polyethylene (*i.e.*, including UHMWPE), then it is my opinion that there is infringement under the doctrine of equivalents because any differences are insubstantial.

53. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™.

54. In my opinion, the "function" of the first fiber-forming material is the same as the function of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**Function of Limitation Under the Doctrine of Equivalents**	**Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

55. My opinion regarding the "function" of the first fiber-forming material is supported by the '446 Patent. The '446 Patent explains that the first fiber forming material is "dissimilar" to the second fiber and the braid of dissimilar yarns provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Tab D at 2:50-52; 3:43-48). Further, the '446 Patent explains that it is possible to "tailor the physical" properties by "varying the type and proportion of each of the dissimilar fiber forming materials used" (Tab D at 2:58-61). Further, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (Tab D at 8:19-21).

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Way" of Limitation Under the Doctrine of Equivalents**	**Way UHMWPE performs its Function in FiberWire™ and TigerWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

intertwining contact" with a yarn from the second set (Tab D at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (Tab D at 2:56-58; 3:43-48). Also, during the prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct "intertwining" contact of dissimilar yarns (December 2, 1992 Office Action at 2, emphasis original).

59. Further, the '446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Tab D at 4:9-59). The '446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (Tab D at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these "preferred embodiments," and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

60. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products have the same "way" as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex's FiberWire™ and TigerWire™ products is

braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex's and Pearsalls' testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Dreyfuss 9/16/05 Dep. at p. 99-107).

61. In my opinion, the "result" of the first forming material is the same as the result of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Result" of Limitation Under the Doctrine of Equivalents**	**Result of UHMWPE in FiberWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

62. My opinion regarding the "result" of the first-forming material is supported by the '446 Patent. For example, the '446 Patent explains that the "heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials" (Tab D at 2:49-52). Further, the '446 Patent states that the "types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties." (Tab D at 1:51-56).

63. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. (Arthrex supplemental response to Interrogatory No. 3) In FiberWire™, when

the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET.

64. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

> Q What did you understand Mr. Grafton to mean when he said:
> "Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
> What did you understand that to mean?
> A Yes, that he wanted a braid which was more -- not so stiff.
> Q As the 100% ultra high molecular weight polyethylene?
> A Yes. (Hallet 1/12/06 Dep. at p. 306:20-307:4, DMI Ex. 324)

> Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
> A Yes. (Hallet Dep. at p. 307:10-14, DMI Ex. 324)

65. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Tab D at 2:58-61).

66. In summary, if it is determined that PE is not PE (does not include UHMWPE), it is my opinion that the ultra high molecular weight polyethylene in Arthrex's FiberWire™ and TigerWire™ suture products is equivalent to the claimed PE because it performs the same function, in the same way to achieve the same result. Any differences are insubstantial in the context of the invention.

VI. Opinions Regarding Contributory Infringement

67. I understand that contributory infringement is defined in 35 U.S.C. §271(c), which provides:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a Patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a Patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

68. I understand that an act of actual direct infringement is necessary for a finding of contributory infringement. If there is direct infringement, then there is contributory infringement if the remaining requirements of the statute are satisfied.

69. I have been asked to provide my opinion as to whether Pearsalls has sold within the United States or imported into the United States a component of a patented suture that constitutes a material part of the invention in claims 1, 2, 8, 9 and 12 of the ‘446 patent. It is my opinion that Pearsalls has sold within the United States or imported into the United States a component of a patented suture constituting a material part of the invention in claims 1, 2, 8, 9 and 12 of the ‘446 patent.

70. It is my understanding that Pearsalls makes all of the braids used in Arthrex’s FiberWire™ and TigerWire™ suture products. (Arthrex’s Response to Mitek Interrogatory #2). Pearsalls imports into the United States unsterile, FiberWire™ and TigerWire™ suture that has not been cut to length or tipped. I personally observed the Pearsalls braided product at the final inspection stage before shipment. Pearsalls also sells within the United States this unsterile, FiberWire™ and TigerWire™ suture to R.K. Manufacturing (Ponton Dep. at p. 17:23-18:12).

71. It is my opinion that the unsterile FiberWire™ and TigerWire™ that Pearsalls imports and sells is a component of the invention of claims 1, 2, 8, 9 and 12 of the '446 Patent. The imported and sold FiberWire™ and TigerWire™ has the same construction as that sold by Arthrex except for some processing operations such as tipping, attachment to anchors or needles, and sterilization. (Ponton Dep. at p. 18:18-21). Thus, the imported and sold FiberWire™ and TigerWire™ has all of the limitations of claims 1, 2, 8, 9, and 12 except that it is not sterilized. It has a braid construction of polyethylene and PET in direct intertwining contact. Further, each has a core except for size 4-0 FiberWire™. Thus, the FiberWire™ and TigerWire™ that is sold and imported by Pearsalls is a component of the claims of 1, 2, 8, 9, and 12 and a material part of the invention of claims 1, 2, 8, 9, and 12.

72. I have been asked to provide my opinion as to whether the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use for infringement of claims 1, 2, 8, 9, and 12 of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use. It is my opinion that the FiberWire™ and TigerWire™ imported and sold by Pearsalls is especially adapted for use in an infringement of the '446 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. The '446 Patent claims a suture. It is my understanding that RK Manufacturing does nothing to alter the FiberWire™ and TigerWire™ surgical braid. (Ponton Dep. at p. 18:18-21). The FiberWire™ and TigerWire™ imported and sold by Pearsalls has no known use other than as a suture, which is claimed in the '446 Patent. Thus, the FiberWire™ and TigerWire™ that is imported and sold by Arthrex is not a staple article of commerce and has no known substantial noninfringing use other than that that has been identified. (Pearsalls' Answers to Mitek's First Set of Interrogatories).

VII. Other Issues

73. It is my opinion that some of the benefits of FiberWire™ and TigerWire™ that are marketed by Arthrex are due to the patented invention, a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the heterogeneous non-bioabsorbable braid.

74. For example, Arthrex markets that FiberWire™ has superior strength, increased stiffness, and has been "enthusiastically endorse[d]" for "its feel." (DMI Ex. 7 at 2). FiberWire™'s and TigerWire™'s ultra high molecular weight polyethylene braided yarns contribute to FiberWire™ and TigerWire™'s strength and stiffness (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 267). Further, FiberWire™'s and TigerWire™'s PET contributes to the flexibility of the braid (DMI Ex. 324). Notably, the patented invention of claims 1, 2, 8, 9, and 12 includes a heterogeneous braid of PE and PET. Further, the '446 patent explains that a heterogeneous braid of dissimilar materials in direct intertwining contact can contribute to the overall properties of the heterogeneous braid (Tab D at 2:50-52; 3:43-48). Further, the '446 patent teaches that the braided yarns can be tailored in type and amounts to obtain the properties of each (Tab D at 2:58-61). FiberWire™ and TigerWire™ do just that by braiding polyethylene and PET. Thus, it is my opinion that benefits touted by Arthrex are due to the patented invention.

75. Arthrex's and Pearsalls' development of FiberWire™ and TigerWire™ confirms my opinion. For example, Mr. Hallet testified that in the development of FiberWire™ he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of

UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

76. It is my opinion that the braiding of dissimilar materials in direct intertwining contact in FiberWire™ contributes to the properties advertised by Arthrex in its marketing literature. For example, Arthrex has marketed that "that FiberWire™ is a "Braided Polyblend Suture" that it is "revolutionizing Orthopaedic Surgery" (DMI Ex. 7 at 1). I also note that Arthrex's claims that its FiberWire™ heterogeneous braid has superior properties is supported by "multiple scientific publications" (DMI Ex. 7 at 2). Thus, Arthrex is highlighting the braiding of dissimilar materials as claimed in claims 1, 2, 8, 9, and 12 of the '446 Patent.

77. Further, Arthrex has made many assertions that FiberWire™'s heterogeneous braid is superior to Ethibond's homogeneous braid. For example, Arthrex claims that the FiberWire™ is "twice as strong" as "polyester suture" (DMI Ex. 9 at 2; DMI Ex. 10 at 2; *see also* DMI Ex. 11; DMI Ex. 24 at ARM001473). Arthrex also asserts that "FiberWire™ has twice the strength of the similar *sized generic suture* with superior feel, tie ability, and lower knot profile" (DMI Ex. 13; emphasis added). Arthrex claims that its studies show that FiberWire™ has better knot strength than "Ethibond Excel braided polyester suture" (ARM002177-8; ARM002181-83; ARM002188-2191). It is my opinion that the braiding of polyethylene and PET in direct intertwining contact contributes to FiberWire™'s properties of strength and flexibility that Arthrex markets with respect to Ethibond.

78. At trial, I may use demonstrative exhibits. For example, I may use demonstrative exhibits to explain the design and construction of Arthrex's FiberWire™ and TigerWire™ suture products, to explain infringement, and to explain the other opinions that I have set forth in my report.

Dated: March 3, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

CERTIFICATE OF SERVICE

I certify that the foregoing Expert Report of Dr. David Brookstein was served by e-mail without exhibits and Federal Express overnight mail (Saturday delivery) with exhibits on March 3, 2006 on the following:

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